



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/295,782 09/12/94 NISHIYAMA

H 188590PCT

EXAMINER

RUSSEL, J

ART UNIT

PAPER NUMBER

7

18M2/0530
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1811

DATE MAILED:

05/30/95

0930/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 2-13-1995 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-9 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-9 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☒ been filed in parent application, serial no. PCT/JP93/00386; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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1. The requirement for Applicants to comply with the Sequence Disclosure Rules mailed January 13, 1995 is withdrawn for the reasons given in Applicants' letter filed February 13, 1995.

2. Claims 1-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 1, line 3, "a" should be inserted after "is" and after "or". In claim 1, the examiner interprets "has suitable substituent(s)" as requiring the presence of a substituent and interprets "may have suitable substituent(s)" as indicating the presence of a substituent is optional. If this interpretation is incorrect, the claim language needs clarification. At claim 1, lines 3, 4, 5, and 6, the word "suitable" is indefinite because the claim does not state for what purpose the substituent is suitable. Without an indication of purpose, it is not clear if any substituent is required, or if -H is a suitable substituent. At claim 1, line 5, "a" should be inserted after "is" and after "or". At claim 1, line 7, "and" should be inserted after the comma. At claim 1, last line, "and" should be changed to "or" so that it is clear that the salt of the compound is an alternative to the compound itself. At claim 2, line 1, "a" should be inserted after "each". At claim 2, line 2, it is not clear what the cyclic amino, dilower alkylamino, or lower alkoxy are. Are they suitable

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substituents? At claim 2, line 3, "and" should be inserted after the comma. At claim 3, line 1, "a" should be inserted after "each". At claim 3, line 2, it is not clear what morpholino, dimethylamino or methoxy are. Are they suitable substituents? At claim 4, line 1, "a" should be inserted after "each". At claim 4, line 2, it is not clear what amino, nitro, or hydroxy are. Are they suitable substituents? At claim 4, line 3, "and" should be inserted after the comma. Periods need to be inserted at the ends of claims 5 and 6. At claim 5, line 2, "Meleu" should be changed to "MeLeu" so that terminology is consistent. At claim 7, line 7, "a" should be inserted after "to" and "an" should be inserted after "by". At claim 7, line 11, "a" should be inserted after "is" and after "or". At claim 7, lines 11-14, it is not clear what the amino, lower alkoxy, and cyclic amino are. Are they substituents of the benzyl groups? At claim 7, line 12, "and" should be inserted after the comma. At claim 7, line 13, "a" should be inserted after "is" and after "or". At claim 7, line 14, the comma should be changed to a period. At claim 8, line 7, "an" should be inserted after "to". At claim 8, line 10, "a" should be inserted after "is" and after "or". At claim 8, lines 10-14, it is not clear what the amino, lower alkoxy, and mono- or di-lower alkylamino are. Are they substituents of the benzyl groups? At claim 8, line 11, "and" should be inserted after the comma. At claim 8, line 12, "a"

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should be inserted after "is" and after "or". At claim 8, line 14, the comma should be changed to a period. At claim 9, line 2, "ingredients" should be changed to "ingredient".

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 9 are rejected under 35 U.S.c. 102(b) as being anticipated by the Japanese Patent Application '796. Assuming that the claimed general formula (I) does not require the presence of substituents on the benzyl groups, or assuming that hydrogen is a suitable substituent (see the above rejection under 35 U.S.C. 112, second paragraph), then the cyclic depsipeptide of the Japanese Patent Application '796 anticipates the claimed compounds of general formula (I).

5. Claims 2-8 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112. The prior art of record does not teach or suggest compounds of the general formula (I) in which A and A^a are benzyl groups substituted with cyclic amino, dilower alkyl amino, lower alkoxy, amino, nitro, hydroxy, and/or mono-lower alkoxy groups, and does not teach or suggest processes of reacting or forming such compounds. There is no motivation in the prior art of record to make such modifications

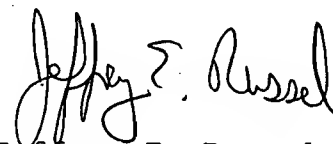
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to the compounds of the Japanese Patent Application '796, and the prior art of record does not provide any basis to predict that such modifications would result in active compounds. Claims drawn to compounds of general formula (I) in which A and A^a are optionally substituted phenyl groups would also be novel and unobvious over the prior art of record.

6. Takagi et al and the European Patent Application '538 are cited to show the general state of the art.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached at (703) 308-4037. The fax number for Art Unit 1811 is (703) 305-7362 and the telephone number for the Group 180 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel
May 25, 1995